

# **EXHIBIT A**

From: CDER DRUG INFO [mailto:DRUGINFO@fda.hhs.gov]  
Sent: Tuesday, April 01, 2008 8:20 AM  
To: aprmd@roadrunner.com  
Subject: Antiepileptic drugs

Dear Dr. Ruggieri:

Thank you for writing to the Food and Drug Administration (FDA). This is in response to your e-mail dated February 8, 2008, to Dr. Steven Galson, regarding your scientific concerns about the recent FDA alert announcing an increased risk of suicidal behavior and suicidal ideation in patients taking antiepileptic drugs. Your e-mail was forwarded to the Division of Drug Information (DDI) for a response.

In the near future, the FDA plans to hold an advisory committee meeting to discuss the current issues involving antiepileptic drugs. The primary purpose of the meeting will be to (1) make public the detailed results of the data analyses, (2) inform the committee of the actions we have taken and why, and (3) seek the committee's advice on whether our actions are appropriate and if any additional measures need to be taken. Our goal is to have the sponsors adopt the labeling changes for antiepileptic drugs by the time the meeting takes place, although we can not predict that this will be the case.

Portions of advisory committee meetings (depending on what is being discussed) are open to the public and oral presentations from the public are welcomed and encouraged. If you feel strongly about the class labeling change being implemented for antiepileptic drugs, I would suggest that you attend and/or present at the upcoming meeting.

If you are interested, please continue to visit <http://www.fda.gov/oc/advisory/default.htm> for information on when the meeting will take place. The Peripheral and Central Nervous System Drugs Advisory Committee will be at least one of the committees involved. The "notice of meeting" will provide the meeting location and instructions if you wish to present. In addition, transcripts and summary of minutes are usually available 30 days after the meeting and are also available from this site.

Concerning your question why data from the FDA Adverse Event Reporting System (AERS) has not been analyzed or made public, the agency does not believe that spontaneous post-marketing reports can be interpreted appropriately in this situation. Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from AERS reports, whether the drug caused them. In the agency's view, the only way to

establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data.

Thank you again for writing. If I can be of assistance in the future, please do not hesitate to contact me.

Sincerely,

Donald Dobbs

Consumer Safety Officer

Division of Drug Information

Office of Training and Communications

Center for Drug Evaluation and Research